

**WHAT IS CLAIMED IS:**

1. A method of determining an individual's predisposition to breast cancer, development of breast cancer and/or responsiveness to therapy  
5 for breast cancer, said method comprising the step of determining the androgen receptor genotype of the individual, thereby determining an individual's predisposition to breast cancer, development of breast cancer and/or responsiveness to therapy for breast cancer.
- 10 2. The method of claim 1, wherein the androgen receptor genotype is determined using a nucleic acid variant in linkage disequilibrium with a CAG repeat in an androgen receptor gene.
- 15 3. The method of claim 2, wherein the androgen receptor genotype is determined by determining the number of CAG repeat within the androgen receptor gene
- 20 4. The method of claim 3, which further comprises a step of amplifying a segment of the androgen receptor using polymerase chain reaction.
- 25 5. The method of claim 4, wherein a pair of primers derived from a nucleic acid sequence of the androgen receptor gene or flanking said gene is used in the polymerase chain reaction.
6. The method of claim 5, wherein the segment of the androgen receptor gene is amplified using a pair of primers as follows:

5'-TCCAGAATCT GTTCCAGAGC GTGC-3' SEQ ID NO:1; and  
5'-GCTGTGAAGG TTGCTGTTCC TCAT-3' SEQ ID NO:2.

7. An assay for screening and selecting an agent which  
5 modulates breast cancer predisposition comprising:  
a) a recombinant androgen receptor gene or functional  
fragment thereof, which comprises the CAG repeat thereof, or a marker in  
linkage disequilibrium therewith; and  
b) assaying a function of said androgen receptor;  
10 wherein an allele which modulates said function of an androgen receptor can be  
selected,  
and wherein a modulation of a function of said androgen receptor is associated  
with a modulation of said breast cancer predisposition, whereby short CAG  
repeat of said AR positively modulates AR receptor function, thereby leading to  
15 breast cancer protection.

8. An assay for screening and selecting an agent which  
modulates breast cancer predisposition comprising:  
a) an expression vector comprising a promoter operably  
20 linked to a reporter gene, said promoter comprising an androgen response  
element, said response element affecting the activity of said promoter upon  
binding thereto of androgen or analog thereof;  
b) a cell expressing a chosen allele of an androgen receptor  
and harboring said vector of a);  
25 c) submitting said cell to at least one agent; and  
d) assaying a level of said reporter gene;  
whereby an agent can be selected when the level of said reporter gene is  
significantly modulated by the presence of said agent.

9. A method of using specific alleles of the androgen receptor gene, or a variant, equivalent, or mutation thereof which shows linkage disequilibrium therewith, to set-up a screening assay for agents destined to modulate androgen receptor function for the purpose of identifying agents involved in breast cancer.
- 5

ART 34 AMDT

- 39 -

14. The method of claim 12, wherein said assay is a *cis-trans* assay.

Add  
a3

T02T03261260